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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Washington, DC 20005-3315

EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11-23-2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,021

Applicant(s)

METZNER ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-34 is/are pending in the application.
- 4a) Of the above claim(s) 20-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 119 and 120.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement (PCT/ISA Form No. 2, Chapter I)
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 18 and 19, drawn to a thrombin preparation, classified in class 435, subclass 214, for example.
- II. Claims 20-31, drawn to a method of making thrombin, classified in class 424, subclass 94.64, for example.
- III. Claims 32 and 33, drawn to a method of using the thrombin preparations of claim 18 and 19, classified in class 424, subclass 447, for example.
- IV. Claim 34, drawn to a method of using the thrombin preparation produced by claims 20-31, classified in class 514, subclass 834, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

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(MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially distinct process such as genetic engineering.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a kit.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a kit or cleaning composition.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Carol Einaudi on 11/8/2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 18 and 19. Affirmation of this election must be made by applicant in replying to this Office

action 42(b) as being drawn to a non-elected invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).

37 CFR 1.97 and 1.98
Sequence Listing (see 37 CFR 1.92 and 1.93)

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is confusing since it is not clear that there are two components to the preparation, namely thrombin and a noncovalently binding inhibitor of thrombin activity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Hanada et al. (Hanada).

Hanada teaches that thrombin is contacted with a dialkyl phosphate, particularly benzamidines such as benzamidine and p-aminobenzamidine which are noncovalently

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binding inhibitors of thrombin activity, see col. 4, lines 10-28. These inhibitors are preferred in applicant's invention. Since claim 18 uses the word "comprising", the claim can encompass more than just the thrombin and the thrombin inhibitor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanada et al. in view of Brezniak et al. and Altshuler.

Hanada teaches that thrombin is contacted with a dialkyl phosphate, particularly in the presence of a surface active agent, which is carried out in the presence of benzamidines such as benzamidine and p-aminobenzamidine which are noncovalently binding inhibitors of thrombin activity, see col. 4, lines 10-67. These inhibitors are preferred in applicant's invention. The surface active agent is noted as being effective in inactivation of viruses. Benzamidine appears to be used as a stabilizer since it is used alternatively to an amino acid which is described as being used as a stabilizer. Amino acids, sodium chloride, and sugar alcohols are noted as being stabilizers for the thrombin. The use of a citrate buffer is also noted for purification/stabilization. Since

thrombin and the thrombin inhibitor.

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Hanada does not teach using calcium salt in its thrombin composition.

Altshuler teaches that sodium chloride, calcium chloride, glycine, etc. are used to aid as a preservative when thrombin is stored, i. e. a stabilizing agent, see col. 2, lines 12-17.

Brezniak teaches that thrombin is stabilized with calcium chloride and sodium chloride, see page 847.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use calcium chloride in the preparation of Hanada since both Altshuler and Brezniak make it clear that calcium chloride is well known to be used as a stabilizer for thrombin and one would want to increase stabilization of the thrombin using well known stabilizers as shown by Altshuler and Brezniak. Further, it would have been obvious since all of the individual components are used to stabilize thrombin, thus to use them together to stabilize thrombin also would have been obvious.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

It is not that one would have had a reasonable expectation of success in producing the claimed

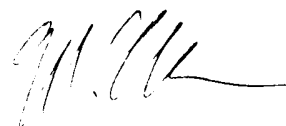
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invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Michael V. Meller
Examiner
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MVM
November 13, 2001